

Product Recall

Atomoxetine Accord 10 mg Hard Capsules, PA2315/019/001
Atomoxetine Accord 18 mg Hard Capsules, PA2315/019/002
Atomoxetine Accord 25 mg Hard Capsules, PA2315/019/003
Atomoxetine Accord 40 mg Hard Capsules, PA2315/019/004
Atomoxetine Accord 60 mg Hard Capsules, PA2315/019/005
Atomoxetine Accord 80 mg Hard Capsules, PA2315/019/006
Atomoxetine Accord 100 mg Hard Capsules, PA2315/019/007

All in-date batches

9th July 2024

Dear Pharmacist,

We wish to advise you that **all in-date batches** of the above products are being recalled with immediate effect.

This recall is to **pharmacy level**. The action has been agreed with the Health Products Regulatory Authority (HPRA).

The reason for the recall is out of specification assay results.

You are requested to please take the following actions:

1. Immediately identify and quarantine any units of these products which you have in your pharmacy. For hospital pharmacists, this includes stock on wards, in clinics and at any other relevant locations within your hospital.
2. Return quarantined units to your supplier, indicating that they are being returned as a result of this recall action. The final date for recalled stock to be received back for credit is 6th August 2024.
3. If you have supplied units of these products to any other pharmacy, clinic or other such establishment, please forward a copy of this recall letter to them, and request they quarantine and return any unused units to you.

Replacement stock is currently unavailable.

Adverse reactions should be reported to Accord (medinfo@accord-healthcare.com) and to the HPRA (medsafety@hpra.ie).

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Accord Healthcare Ireland Ltd. at telephone number +353 21 4619040 or email qa_ireland@accord-healthcare.com.

Yours sincerely,



Wojciech Kisiel, Responsible Person